MAY 15 2014



# 510(k) Summary
per 21 CFR §807.92 (c)

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| **Submitter's Name and Address** | Boston Scientific Corporation<br>One Scimed Place<br>Maple Grove, MN 55311 |
| **Contact Name and Information** | Mark Murphy<br>Senior Regulatory Affairs Specialist<br>Tel: 763.494.2377<br>Fax: 763.494.2222<br>E-mail: mark.murphy2@bsci.com |
| **Date Prepared** | February 7, 2014 |
| **Trade Name** | Renegade™ HI-FLO™ FATHOM™ Kit<br>Renegade™ HI-FLO™ FATHOM™ System<br>Renegade™ HI-FLO™ Microcatheter<br>Renegade™ HI-FLO™ Kit |
| **Common Name** | Catheter, Continuous Flush |
| **Classification** | Class II per 21 CFR Part 870.1210<br>Product Code: KRA<br>Classification Panel: Cardiovascular |
| **Predicate Device** | Renegade™ HI-FLO™ FATHOM™ Kit<br>(K100892, 12 April 2010)<br><br>Renegade HI-FLO Microcatheter and Kit<br>(K000177, 07 April 2000) |
| **Device Description** | The Boston Scientific Renegade HI-FLO Microcatheter devices are single lumen, multipurpose catheters intended for use in the peripheral vasculature. The basic operating principle is to advance the microcatheter through a guide catheter and track coaxially over a steerable guidewire in order to access the treatment site. Once the target region has been accessed, the microcatheter can be used to deliver diagnostic, embolic, or therapeutic materials into vessels. |

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| **Device Description (cont'd)** | The Renegade Hi-Flo Microcatheter incorporates a taper in its outside diameter along its length from the 3.0F (1.0 mm) proximal outer diameter (OD) to the flexible 2.8F (0.93 mm) distal OD. The inner diameter (ID) of the microcatheter is 0.69 mm (0.027 in) minimally in the proximal and distal regions. The microcatheter lumen is able to accommodate steerable guidewires that are ≤ 0.47 mm (0.018 in) in diameter. The microcatheter is available in 80, 105, 115, 135, and 150 cm usable lengths.<br><br>The distal end of the microcatheter is coated with Hydro Pass™ hydrophilic coating for lubricity. The Renegade Hi-Flo Microcatheter has a radiopaque marker at the distal tip to facilitate fluoroscopic visualization. The distal tip of the microcatheter is steam shapeable and can be bent to the desired geometry with a steam shaping mandrel accessory packaged with the device. The proximal end of the microcatheter incorporates a hub with a standard luer to facilitate the attachment of accessories. |
| **Indication for Use** | **Renegade HI-FLO FATHOM Kit / System:**<br><br>The Renegade HI-FLO FATHOM Kit / System is intended for peripheral vascular use. The FATHOM guidewire can be used to selectively introduce and position the Renegade HI-FLO microcatheter in the peripheral vasculature. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels.<br><br>**Renegade HI-FLO Microcatheter and Kit:**<br><br>The Renegade HI-FLO Microcatheter is intended for peripheral vascular use. The microcatheter can be coaxially tracked over a steerable guidewire in order to access distal, tortuous vasculature. Once the subselective region has been accessed, the microcatheter can be used for the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels. Diagnostic, embolic, or therapeutic agents to be used in accordance with specifications outlined by the manufacturer. |
| **Comparison of Technological Characteristics** | The Renegade HI-FLO Microcatheters are similar in fundamental design, function, device materials, packaging, sterilization, operating principle, intended use / indication for use and fundamental technology as the predicate devices. The modification from the predicate device included a change to the braided shaft material. |

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| **Non-Clinical Performance Data** | The following bench testing was conducted for design elements and performance characteristics deemed appropriate to demonstrate equivalence to the predicate device. The Renegade HI-FLO Microcatheters met the predetermined acceptance criteria ensuring substantial equivalence to the predicate device. No new safety or performance issues were raised during testing.<br>• Static Burst Pressure<br>• Dynamic Burst Test (Infusion Pressure)<br>• Catheter Distal Joint Tensile Strength<br>• Hub to Shaft Tensile Strength<br>• Kink Radius of Curvature<br>• Distal OD Reduction<br>• Distal Tip Flexibility<br>• Proximal Shaft Stiffness<br>• Radiopacity |
| **Clinical Performance Data** | Not applicable; determination of substantial equivalence is not based on an assessment of clinical performance data. |
| **Conclusion** | Boston Scientific has demonstrated that the modification made to the Renegade HI-FLO Microcatheters are substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principle, and intended use / indication for use as the predicate devices. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 15, 2014

Boston Scientific Corporation
Mr. Mark Murphy
Senior Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K140329
Trade/Device Name: Renegade HI-FLO Microcatheter, Renegade HI-FLO Microcatheter Kit, Renegade HI-FLO FATHOM System, Renegade HI-FLO FATHOM Kit
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: April 14, 2014
Received: April 15, 2014

Dear Mr. Murphy,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kenneth J. Cavanaugh -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):** K140329

| Device Name | Indication For Use |
|---|---|
| Renegade HI-FLO FATHOM Kit | The Renegade HI-FLO FATHOM Kit / System is intended for peripheral vascular use. The FATHOM guidewire can be used to selectively introduce and position the Renegade HI-FLO microcatheter in the peripheral vasculature. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels. |
| Renegade HI-FLO FATHOM System | |
| Renegade HI-FLO Microcatheter | The Renegade HI-FLO Microcatheter is intended for peripheral vascular use. The microcatheter can be coaxially tracked over a steerable guidewire in order to access distal, tortuous vasculature. Once the subselective region has been accessed, the microcatheter can be used for the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels. Diagnostic, embolic, or therapeutic agents to be used in accordance with specifications outlined by the manufacturer. |
| Renegade HI-FLO Kit | |

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of Center for Devices and Radiological Health (CDRH)

Kenneth J. Cavanaugh -S